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510 K Summary

AUG 2 4 2004

according to 21 CFR 807.92

A1 Address

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Contact Name: Mr. Markus Buetler
Tel: 001 41 41 766 4252
Date: 21.th November 2003

A2 Device Name

1. Trade Name: ARGUS PB-2200
2. Common Name: Monitoring System

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:

ARGUS PB-1000 System K 012226

A4 Intended Use

The Monitoring System ARGUS PB-2200 is for the monitoring of vital parameters such as:

Invasive Blood Pressure: systolic, distolic and mean pressure
CO_2, etCO_2 and CO_2ins, main and/or sidestream
FIO2

It will extend the functionality of the existing Argus PB –1000 System (K012226)
The system comprises the Parameter Box PB-1000 and the Visualisation Unit ARGUS PRO. The two units are connected via a serial interface.
All vital parameters and evaluations are registered and calculated in the PB-1000. This data is then transmitted to the visualisation unit ARGUS PRO or another generally used PC via the serial interface. All data can be shown and monitored on the ARGUS PRO.
The PB-1000 operated using an internal battery and an external power input (RS 232/12V), which is, like the data transmission, completely separate from the visualisation unit. The ARGUS PRO is powered via the normal mains connection 230V/110V.
The system is intended for use in the Intensive Care Unit, in the Recovery Room, in the Operation Room and during hospital internal transport.

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A5 Table of Comparison

	Argus PB-1000 System (K012226)	ARGUS PB-2200
Dimensions:	210x115x45mm	210x115x64.5mm 1)
Weight:	980 g	1200g 2)
Environmental Conditions:		
Operating temperature	+10° - 40° C	same
Storage temperature	-10° - +50° C	same
Relative humidity	25% - 95% (non condensing)	same
Electrostatic Discharge / Electromagnetic Compatibility:	EN 60601-1-2	same
ESD	Fully functional below 4 kV (Open Air)	same
	No damage below 8 kV (Open Air)	same
Radiated Emissions	Less than 30 dB Microvolts	same
Radiated Immunity	Less than 3 Volts per meter	same
Safety Standards		
Safety of Medical Electrical Equipment part1. General requirements	EN 60601-1:1990	same
Safety requirements for medical systems	EN 60601-1-1:1993	same
Safety requirements for programmable electrical medical systems	EN 60601-1-4:1996	same
Requirements for the safety of the blood pressure monitoring equipment	EN 60601-2-34:1995	same

Discussion of Differences:
None of the above differences (1 or 2) can be considered as safety relevant differences.
We consider the submitted device to be as safe and effective as the Predicate ARGUS PB-1000 System (K012226) device.

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B1 Non-Clinical Tests

1. Electrical Safety and Reliability
   The device has been tested to be in accordance with the following standards:
   EN 60601-1:1990: *Safety of Medical Electrical Equipment part 1, General requirements.*
   EN 60601-1-1:1993 *Safety requirements for medical electrical systems.*
   EN 60601-1-2: *Electromagnetic Compatibility Test, Electrostatic Discharge, Radio Frequency Electromagnetic Field, Fast Transients.*
   EN 60601-1-4:1996 *Collateral Standard: Programmable electrical medical systems.*
   EN 60601-2-34:1995 *Particular requirements for the safety of the blood pressure monitoring equipment.*

   All tests are passed.

4) Data related to software quality
   SCHILLER has reviewed its software development process following the guideline
   " reviewer guidance for computer controlled medical devices undergoing 510 (k) review". Device software requirements, software structure chart, software development, software revision/ modification, software identification, software verification, validation and testing are described in the data attached.

B2 Clinical Tests

n.a.

B3 Conclusions from Tests

The fulfilling of the above standards ensures the safety and effectiveness of the submitted device. We consider the submitted device to be as safe and effective as the Predicate ARGUS PB-1000 System Device. (K 012226)

Date: 21.11.2003

Markus Buetler
Quality Assurance Manager
SCHILLER AG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2004

Mr. Markus Buetler
Quality Assurance Manager
SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Re: K033738
Trade Name: ARGUS PB-2200 Patient Monitoring System
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II (two)
Product Code: DSK
Dated: August 2, 2004
Received: August 4, 2004

Dear Mr. Buetler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033738

Device Name: Monitoring System ARGUS PB-2200

Indications For Use:
The monitoring system ARGUS PB-2200 is for the monitoring of vital parameters such as:

Invasive blood pressure: systolic, diastolic and mean pressure
CO_2, etCO_2 and CO_2ins, main and/or sidestream
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033738